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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,259	09/23/2006	Robert D. Kross		6322

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EXAMINER

HOLT, ANDRIAE M

ART UNIT	PAPER NUMBER
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1616

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02/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,259	KROSS, ROBERT D.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3

- 10599259 - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/23/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 are pending in the application. Claims 1-20 will presently be examined to the extent they read on the elected subject matter of record.

Priority

Claims 2 and 11 of the instant application are not granted benefit of the following continuation parent application, 60/555,562 filed on March 24, 2004, because this application lacks support and any disclosure for "interpenetrating polymer system is comprised of Polyacrylate-18 and Polyacrylate-19": **The effective filing date of the claims 2 and 11 of the instant application is March 23, 2005.**

Priority to PCT/US2005/009650 filed on March 23, 2005, which claims priority to U.S. Provisional Application No. 60/555,562 filed on March 24, 2004 is acknowledged for claims 1, 3-10, and 12-20.

Information Disclosure Statement

Receipt of Information Disclosure Statements filed on September 23, 2006, is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cahill et al. (US 5,998,500).

Cahill et al. disclose one aspect of the invention relates to a filter tow of an Interpenetrating Polymer Network (IPN) formed of at least two polymers which are substantially water soluble in their salt form and which ionically interact (bimodal interpenetrating polymer). These two polymers are designated Polymer I and Polymer II. Polymer I, preferably an anionic polymer, preferably is water soluble and in its salt form, (e.g., NaA), the sodium salt in this case (anionic functionality). The monomer of Polymer II preferably is cationic, and preferably is also water soluble and in its salt form (cationic functionality). The two polymers are connected or bonded by ionic interactions to form the IPN. The IPN is used to form fibers, which are in turn used to form the filter tow which, upon disposal following use, is sufficiently water soluble to biodegrade. (col. 3, lines 34-48). It is duly noted that the composition of the prior art is the same as Applicant's composition. Thus, the skilled artisan would recognize that a composition is inseparable from its properties. Hence, all the properties associated with Applicant's composition would also be possessed by the composition of the prior art. Therefore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use; then it meets the claim. The IPN network disclosed by

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Cahill et al. would be able to provide cow udder protection as the composition is the same as the composition of the instant application.

Cahill et al. meet all the limitations of the claim and thereby anticipate the claim.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Su (US 4,501,834).

Su discloses the formation of novel water soluble and water insoluble gels by interpolymer reactions of selective anionic polymers with selective cationic polymers in an aqueous medium, with either polymer serving as a cross-linking agent under specific conditions of speed and concentration (bimodal interpenetrating polymer)(Abstract). Su discloses the gels can be used in sewage treatment, in the making of clear films, and as a conditioning and gelling agent in personal care compositions such as shaving gels, shampoos, and the like (col. 2, lines 24-27). Su discloses to achieve the objects of the invention the novel water soluble and water insoluble swellable interpolymer gels comprises the reaction product formed by the rapid and intensive interaction of two oppositely charged selective polymers (col. 2, lines 51-57). Su discloses the oppositely charged polymers are a quaternized cationic polymer bearing positive charges (cationic functionality) and an anionic polymer bearing negative charges selected from the group consisting of polysulfonic acid and an alginic acid (anionic functionality) (col. 2, lines 58-62). Su discloses the intermolecular reactions of anionic polymers and cationic polymers result in the formation of gels of various types ranging from water soluble to water insoluble depending upon the reaction conditions and the reactant polymer

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structures (col. 6, lines 19-23). Su discloses in example 2, col. 9, lines 45-68-col. 10, lines 1-15, each of the above-identified samples was diluted to 100 g by weight with deionized water and the viscosity of the resultant interpolymer solution was determined using a Brookfield RVF Viscometer. Su discloses a #3 spindle was used with viscosities ranging from 620-4050 cps. Su further discloses the clear gels are thixotropic because the viscosity increases as the shear rate is decreased. It is duly noted that the composition of the prior art is the same as Applicant's composition. Thus, the skilled artisan would recognize that a composition is inseparable from its properties. Hence, all the properties associated with Applicant's composition would also be possessed by the composition of the prior art. Therefore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use; then it meets the claim. The product from the interpolymer reactions, interpolymer gels disclosed by Su would be able to provide cow udder protection as the composition is the same as the composition of the instant application.

Su meets all the limitations of the claims and thereby anticipate the claims.

Claims 1, 3, and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Wolff et al. (US 2007/0197729).

Wolff et al. disclose bimodal polymer compositions and personal care fixatives containing bimodal polymer compositions. Wolff et al. disclose a bimodal polymer

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composition having a first polymer with anionic character and a second polymer with cationic character and wherein the polymers form an interpenetrating polymer network (bimodal polymer composition having both cationic and anionic functionalities). Wolff et al. further disclose the compositions include personal care fixatives (e.g., health care, hygiene or cosmetic compositions) containing the bimodal polymer composition (Abstract). The personal care fixative can include the bimodal polymer composition and a cosmetically acceptable medium (dermatologically-compatible solvent). The cosmetically acceptable medium can include one or more relatively volatile solvents such as water or an alcohol. Wolff et al. disclose in addition, in some embodiments, the cosmetically acceptable medium also includes an alcohol such as ethanol or panthenol (non-cytotoxic and non-irritating to mammalian skin, ethanol). Wolff et al. further disclose the personal care fixative can contain any of the personal care fixative additives known to those of skill in the art. For example, the personal care fixative further can contain at least one component selected from the group consisting of thickening agents, dispersing agents, emulsifiers, emollients, stabilizers, surfactants, fragrances, preservatives, proteins, conditioners, colorants, dyes, plasticizers, neutralizers, glossifiers and propellants (page 4, paragraph 40). Wolff et al. disclose application of the personal care fixatives typically produces a polymer film. The polymer film can be principally composed of the bimodal polymer composition (page 4, paragraph 41).

Wolff et al. disclose in example 4 pump compositions consisting of a bimodal polymer composition that is 20% of the composition and ethyl alcohol (ethanol). It is

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duly noted that the composition of the prior art is the same as Applicant's composition. Thus, the skilled artisan would recognize that a composition is inseparable from its properties. Hence, all the properties associated with Applicant's composition would also be possessed by the composition of the prior art. Therefore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use; then it meets the claim. The bimodal interpenetrating polymer system disclosed by Wolff et al. would be able to provide cow udder protection as the composition is the same as the composition of the instant application.

Wolff et al. meet all the limitations of the claims and thereby anticipate the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-10, 12-14, and 18-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ehrhard et al. (US 6,440,442) in view of Su (US 4,501,834).

Applicant's Invention

Applicant claims a composition and a method for dry cow udder protection comprising a bimodal interpenetrating polymer system having both cationic and anionic

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functionalities and capable of forming a stable aqueous solution and ionic bonds between polar chains. Applicant claims the method of protection comprises applying an aqueous solution containing a bimodal interpenetrating polymer system to a cow teat.

**Determination of the scope of the content of the prior art
(MPEP 2141.01)**

Ehrhard et al. teach a mammalian teat dip composition capable of being used during the mammal's dry period comprising a solution of a film-forming polymer blend comprising a first polymer component which is an organic, solvent-soluble, preformed, thermoplastic polyurethane having no reactive isocyanate groups and a second polymer component which is hydrophilic poly (N-vinyl lactam) and at least one antimicrobial agent (Abstract) (bimodal polymer and antimicrobial agent). Ehrhard et al. teach upon application to mammalian skin, this composition leaves a long-lasting, water-resistant, residual, elastic film. Ehrhard et al. teach the composition exhibits barrier and antimicrobial properties against mastitis-causing pathogenic, thereby protecting the mammal from environmental pathogens (col. 2, lines 37-44). Ehrhard et al. teach examples of antimicrobial agents include iodine, chlorhexidine, bronopol, and triclosan (iodine, chlorhexidine, bronopol, and triclosan) (col. 2, lines 66-67). Ehrhard et al. teach the composition can also contain water-soluble or water-dispersible skin conditioning agents, such as glycerin; and glycols; such as polyethylene glycol (col. 3, lines 18-20).

Ehrhard et al. teach a method of protecting a mammalian teat from infection by applying the compositions to the mammalian teat and evaporating the solvent portion of the composition to form a protective water-resistant film (col. 3, lines 24-30). Ehrhard et al. teach the compositions can be applied to skin as a solution in a dermatologically-

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acceptable volatile solvent. Ehrhard et al. further teach dermatologically-acceptable solvents are non-cytotoxic and non-irritating to mammalian skin. Ehrhard et al. teach examples of solvents include ethanol, isopropanol, ethyl lactate, diacetone alcohol, n-methyl pyrrolidone and mono and di-ethylene glycol ethers (col. 5, lines 5-12) (dermatologically-compatible solvent). Ehrhard et al. teach in some embodiments, buffering agents can be utilized. Ehrhard et al. teach these agents include the acid form and the base form of an organic or inorganic acid to produce a resultant pH value of about 4 to about 8 (adjust pH). Ehrhard et al. teach the pH range is adjusted with sodium bicarbonate (col. 5, lines 52-58). Ehrhard et al. teach the viscosity of the composition ranges from about 500-5000 cP (viscosity). Ehrhard et al. teach this range in the viscosity allows an adequate amount of the composition to remain on the mammalian teat when applied without being overly viscous which make application difficult by dipping or other methods (col. 5, lines 66-67-col. 6, lines 1-4). Ehrhard et al. teach the compositions contain various viscosity enhancers or thickeners. Ehrhard et al. teach thickeners that can be used include natural gum such as xanthan gum or silica (xanthan gum and silica) (col. 6, lines 5-13).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Ehrhard et al. do not teach the use of a bimodal interpenetrating polymer system that has both cationic and anionic functionalities as the film-forming polymer. It is for this reason Su et al. is added as a secondary reference.

The teachings of Su et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

**Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Ehrhard et al. and Su et al. and use a bimodal interpenetrating polymer system that has both cationic and anionic functionalities as the film forming polymer. Ehrhard et al. teach a mammalian teat dip comprised of a film forming polymer that is a bimodal system, two polymers, and at least one antimicrobial agent. One skilled in the art at the time the invention was made would have been motivated to use the bimodal polymer system that is taught by Su et al. because Su teaches the intermolecular reactions of anionic polymers and cationic polymers result in the formation of gels of various types ranging from water soluble to water insoluble depending upon the reaction conditions and the reactant polymer structures that form clear films. It would have been obvious to the skilled artisan to try polymers as taught by Su et al. in the formulations as it is known in the art to use film forming polymers to form protective barriers to protect mammalian teats and udders from mastitis forming pathogens.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Claims 1-14 and 18-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ehrhard et al. (US 6,440,442) in view of Wolff et al. (US 2007/0197729) and the Syntran® PC 5107 Technical Data Sheet.

Applicant's Invention

Applicant claims a composition and a method for dry cow udder protection comprising a bimodal interpenetrating polymer system having both cationic and anionic functionalities and capable of forming a stable aqueous solution and ionic bonds between polar chains. Applicant claims the method of protection comprises applying an aqueous solution containing a bimodal interpenetrating polymer system to a cow teat.

Determination of the scope of the content of the prior art (MPEP 2141.01)

The teachings of Ehrhard et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Ehrhard et al. do not teach the use of a bimodal interpenetrating polymer system that has both cationic and anionic functionalities as the film-forming polymer or that the system is comprised of Polyacrylate-18 and Polyacrylate-19. It is for this reason Wolff et al. and Syntran® PC 5107 Technical Data Sheet are added as secondary references.

The teachings of Wolff et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

The Syntran PC® 5107 technical Data Sheet teaches that Syntran® PC 5107 is an acrylate copolymer that is comprised of polyacrylate 18 and polyacrylate-19. Syntran® PC 5107 is used as fixatives and film formers.

**Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Ehrhard et al. and Wolff et al. and use a bimodal interpenetrating polymer system that has both cationic and anionic functionalities as the film forming polymer. Ehrhard et al. teach a mammalian teat dip comprised of a film forming polymer that is a bimodal system, two polymers, and at least one antimicrobial agent. One skilled in the art at the time the invention was made would have been motivated to use the bimodal polymer system because Wolff et al. teach a bimodal polymer composition having a first polymer with anionic character and a second polymer with cationic character and wherein the polymers form an interpenetrating polymer network (bimodal polymer composition having both cationic and anionic functionalities) that can be used as personal care fixatives, such as health care and hygiene compositions. It would have been obvious to the skilled artisan to try polymers as taught by Wolff et al. in the formulations as it is known in the art to use film forming polymers to form protective barriers to protect mammalian teats and udders from mastitis-forming pathogens.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Ehrhard et al., Wolff et al., and the Syntran® PC 5107 Technical Data Sheet and use Polyacrylate 18 and Polyacrylate 19 as the specific bimodal interpenetrating polymer system. One skilled in the art at the time the invention was made would have been motivated to use the bimodal polymer system because Wolff et al. teach a bimodal polymer composition having a first polymer with anionic

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character and a second polymer with cationic character and wherein the polymers form an interpenetrating polymer network (bimodal polymer composition having both cationic and anionic functionalities) that can be used as personal care fixatives, such as health care and hygiene compositions. As such, the skilled artisan would have been motivated to use Polyacrylate 18 and polyacrylate-19 as the polymer components of the bimodal polymer because the Technical DataSheet teaches that polyacrylate-18 and polyacrylate-19 are acrylate copolymers (bimodal) that are used as fixatives and film-formers. Therefore, it would have been obvious to the skilled artisan to try polymers as taught by Wolff et al., particularly, polyacrylate-18 and polyacrylate-19 because it is known in the art to use film forming polymers to form protective barriers to protect mammalian teats and udders mastitis-forming pathogens.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Claims 1, 3-10, and 12-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ehrhard et al. (US 6,440,442) in view of Wolff et al. (US 2007/0197729) and Li Publication.

Applicant's Invention

Applicant claims a composition and a method for dry cow udder protection comprising a bimodal interpenetrating polymer system having both cationic and anionic functionalities and capable of forming a stable aqueous solution and ionic bonds

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between polar chains. Applicant claims the method of protection comprises applying an aqueous solution containing a bimodal interpenetrating polymer system to a cow teat.

Applicant claims the viscosity of the formulation is adjusted by adjusting the pH.

**Determination of the scope of the content of the prior art
(MPEP 2141.01)**

The teachings of Ehrhard et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Ehrhard et al. and Wolff et al. do not teach the viscosity of the formulation is adjusted by adjusting the pH. It is for this reason the Li Publication is added as secondary a references.

The teachings of Wolff et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

The Li Publication teaches the viscosity behavior as a function of pH for hydrophobically modified terpolymers of acrylamide and acrylic acid is strongly dependent on the polymer solution concentration. The Li Publication teaches that in dilute polymer solution, hydrophobic associations are mainly intrapolymer, whereas in high polymer concentration, polymer chains form entangled complexes and interpolymer interactions are prominent. The Li Publication teaches previous reports in

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the literature for dilute solution conditions have demonstrated a decrease in viscosity of similar polymer systems when the pH is raised from acidic conditions. On the other hand, for the relatively concentrated polymer solutions studied in this work, when the degree of ionization of the AA fraction is raised by raising the pH of the solution, interpolymer interactions and network formation lead to a remarkably large viscosity increase due to a combination of hydrophobic interactions of hydrogen bonding. The Li Publication teaches at pH 7, depending on the size of the hydrophobe, gel-like systems are obtained. The Li Publication teaches the solution pH plays an important role in viscosity enhancement (page 10051, Conclusion).

**Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Ehrhard et al., Wolff et al., and the Li Publication and adjust the viscosity of the formulations by adjusting the pH. Ehrhard et al. teach a mammalian teat dip comprised of a film forming polymer that is a bimodal system, two polymers, and at least one antimicrobial agent. Ehrhard et al. teach that the pH of the compositions can be adjusted. One skilled in the art at the time the invention was made would have been motivated to use the adjustment of the pH to adjust the viscosity of the formulations because the Li Publication teaches that pH of solution plays an important role in viscosity enhancement. As such, it would have been obvious to the skilled artisan that adjusting the pH of the compositions would adjust the viscosity of the aqueous polymer solutions because this is a known practice in the art as referenced and verified by the Li Publication.

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Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616